

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

FEDERAL AGENCIES FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF FUEL CYCLE AND MATERIAL SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIAL SECTION 8
631 PARK AVENUE
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
MATERIAL RADIATION PROTECTION SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
799 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
MATERIAL RADIATION PROTECTION SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94596

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☒ A. NEW LICENSE
☐ B. AMENDMENT TO LICENSE NUMBER _____
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Boehringer Mannheim Diagnostics
9115 Hague Road
Indianapolis, IN 46250
ATTN: Iva Sue Smith

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Boehringer Mannheim Diagnostics
9115 Hague Road
Indianapolis, IN 46250

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Iva Sue Smith

TELEPHONE NUMBER
317-845-2386

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND

8509110221 850801
REG 3 LIC 30
13-24532-01 PDR

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY 3M AMOUNT ENCLOSED \$ 700.00

13. CERTIFICATION (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN, IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE—CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Iva Sue Smith

Iva Sue Smith

Manager, Regulatory Affairs 6/17/85

14. VOLUNTARY ECONOMIC DATA

a. ANNUAL RECEIPTS

<\$250K	\$1M-3.5M
\$250K-500K	\$3.5M-7M
\$500K-750K	\$7M-10M
\$750K-1M	>\$10M

b. NUMBER OF EMPLOYEES (Total for entire facility excluding outside contractors)

c. NUMBER OF BEDS

d. WOULD YOU BE WILLING TO FURNISH COST INFORMATION (Dollar and/or staff hours) ON THE ECONOMIC IMPACT OF CURRENT NRC REGULATIONS OR ANY FUTURE PROPOSED NRC REGULATIONS THAT MAY AFFECT YOU? (NRC regulations permit it to protect confidential commercial or financial—proprietary—information furnished to the agency in confidence)

☐ YES

☐ NO

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

APPROVED BY

AMOUNT RECEIVED

CHECK NUMBER

CONTROL NO. 7 928 1:

DATE

APPLICATION FOR MATERIAL LICENSE

ITEMS 5 THROUGH 12

5. Element and Mass: I¹²⁵

Chemical and/or Physical Form: Commercially available immunoassay I¹²⁵ labeled kits.

Name of Manufacturer and Model #: N/A

Maximum Number of Millicuries and/or sealed sources and maximum activity per source which will be possessed at any one time: 200 uCi or .2 millicuries of in-vitro diagnostic products.

- 6 The immunoassay diagnostic test kits will be utilized in the laboratory for method comparison studies.
7. Miss Patricia Ann Jemison will be responsible for the Radiation Safety Program and will be the RSO. Miss Jemison's Curriculum Vitae is attached.
8. The RSO will be responsible for training individuals working in the laboratory as required by 10 CFR Part 20.
9. A diagram of the laboratory is included in the application. The equipment to be utilized in accordance with this license is as follows:

<u>Type of Instrument</u>	<u>Manufacturer's Name</u>	<u>Model Number</u>	<u>Number Avail.</u>	<u>Radiation Detected</u>	<u>Sensitivity Range</u>
1. Scintillation Spectrometer	Packard	PGDD S/N 00297	1	Gamma	50-9,000,000 cpm
2. Survey Meter (on order)	Ludlum	Model 3 Model 44-3	1 1	I ¹²⁵	0-5K cpm

10. The Radiation Safety Program is included in this application.

11. Waste Management:

Liquid waste will be disposed of in the sanitary sewer system in accordance with 20.303 of 10 CFR, Part 20.

PATRICIA ANN JEMISON
5111 Rosslyn Avenue
Indianapolis, Indiana 46205
(317)259-4468

OBJECTIVE: Research position for a medically oriented company.

QUALIFICATIONS: Nine years experience in both research and clinical labs.
Close associations with physicians and faculty members.

ACHIEVEMENTS: Planned, organized and implemented Microbiology teaching
labs for medical, dental and nursing students.

Planned, organized and implemented the clinical Chlamydia
lab for CAP certification.

Publications:

G.E. Klein, P. Jemison, R.A. Haak and A.G. Matthyse,
Physical Evidence of a Plasmid in *Rhizobium japonicum*,
Separatum EXPERIENTIA 31, 532 (1975).

Robert B. Jones and Patricia A. Jemison, Two Dimensional
Electrophoresis of Opaque and Transparent Variants of
Neisseria Gonorrhoeae. Current Chemotherapy and Infectious
Disease, Proceedings of the 11th ICC and the 19th ICAOC,
American Society of Microbiology, 1980.

Robert B. Jones, Patricia A. Jemison, Wilbert J. Newhall,
V. and Richard A. Haak, Resolution of Basic Gonococcal
Outer Membrane Proteins by Nonequilibrium pH Gradient
Electrophoresis, *Infection and Immunity*, Dec. 1980.

EXPERIENCE: Technical Sales Representative, Serono Diagnostics.
Selling RIA diagnostic kits, bulk reagents, gamma counters
plus computer data reduction systems to hospital and
reference labs. Territory includes western New York,
western Pennsylvania, central and north-eastern Ohio and
a small section of West Virginia. (1983 -)

Assistant Product Manager, May, 1983 - August, 1983,
Marketing Research Analyst, May, 1982 - May, 1983, BetaMED
Pharmaceuticals. Organize and coordinate evaluation of
diagnostic tests, evaluate market potential of Pharmaceutical
products and equipment. Closely involved in the preparation
of a 510 (K) application for a diagnostic product.
Responsible for complete preparation of a Small Business
Innovative Research Grant Application for the NIH. Part
time securities salesperson beginning September, 1981.
(1982-1983)

EXPERIENCE:
(continued)

Lab Supervisor, Department of Infectious Diseases, I.U. Medical Center. Supervision of 4-5 Technicians doing clinical chlamydia cultures plus research projects with chlamydia and gonorrhoea. Complete preparation of all materials needed to perform clinical chlamydia cultures, plus materials needed for Micro-immuno-fluorescent test to detect chlamydial antibodies in clinical and research patients. Testing of all monoclonal antibodies produced against chlamydia. ^{125}I labeling of outer membrane proteins. Antibiotic synergy tests, emergence of antibiotic-resistant chlamydia. SDS-PAGE on outer membranes of chlamydia and gonorrhoea. Write all protocols and lab manuals needed for lab, plus ordering of all equipment and materials needed. (1978-1982)

Medical Technologist, Department of Clinical Pathology, I.U. Medical Center. Laboratory analysis of blood, urine, and spinal fluid specimens in Chemistry and Hematology, specimen set-up in bacteriology Stat Lab, and deglycerolization of frozen RBC's for transfusions. (1977-1978)

Departmental Lab Technician, Department of Microbiology, I.U. Medical Center. Coordinate and prepare teaching labs for medical, dental and nursing students. Ordering of all media and equipment needed for labs. Redesign experiments used in labs. Supervision of six technicians in media and glassware preparation. Teaching assistant in nursing lab. (1974-1977)

Research Technician, Department of Microbiology, I.U. Medical Center. Preparation and maintenance of plant tissue cultures and reagents. Extraction of DNA from plant and bacterial cells for DNA-DNA hybridizations, calcium chloride-ethidium bromide equilibrium density gradients. ^{32}P labeling of bacterial DNA. Ordering of all supplies needed. Occasional morphology and metabolic pathway characterizations of bacteria used in lab. (1973-1974)

EDUCATION:

B.A. Degree, Indiana University. Major: Zoology. Minors: Microbiology and Chemistry.

Radiation Safety Course, 1973.

COMMUNITY
ACTIVITIES:

Jordan YMCA Masters Swim Team. Jordan YMCA "Learn to Swim" instructor.

PERSONAL DATA:

Birth Date: August 27, 1951
Health: Excellent
Marital Status: Single
Assertive, Self-Motivated, People Oriented

STANDARD OPERATING PROCEDURE #1

WIPE TEST MONITORING PROCEDURE FOR RADIOACTIVITY

Purpose: To monitor the amount of residual radioactivity in the Immunology Laboratory work area.

Material: 12 x 75 mm polystyrene culture tubes
Cotton tipped wooden swabs
Packard gamma counter

- Procedure:
- 1) Swab each area indicated on the diagram, then place the swab in a tube labeled to match the corresponding area on the diagram. Leave one tube empty to be used for background counts (Place unused swab in tube). After swabbing an area, break the swab off even with the top of the tube.
 - 2) Place all the tubes into the Packard gamma counter racks and load the racks onto the instrument. Run tubes on program 5.

Parameters for Program 5

Assay Number: 5
Radionuclid: ^{125}I
Time: 1.0
Count Mode, All/Odd/Even: 0
Background: 0
Screening: 0
CPM/Dose: 0

- 3) After printout is complete, check all counts against the count of the blank tube with swab. Any area with more than twice the counts of the blank with swab should be decontaminated and rewiped.
- 4) Decontamination: On benches with paper on top, replace paper. On other surfaces, use Radiowash according to directions on can.
- 5) Enter results in wipe test book.
- 6) To be performed monthly.

LUDLUM MODEL 3 AND MODEL 44-3 CALIBRATION PROCEDURE

CALIBRATION OF MODEL 3

1. Hookup Model 3 to Pulser.
2. Set Pulser to read 400 CPM (this should be 80% of the full scale).
3. Check sensitivity, should be 40 millivolts (+20mV, -16mV).
4. Set Model 3 range at X0.1 and set pulser multiplier at 1. Adjust X0.1 range until Model 3 reads 400 CPM.
5. Set Model 3 range at X1 and set pulser multiplier at 10. Adjust X1 range until Model 3 reads 4K CPM.
6. Set Model 3 range at X10 and set pulser multiplier at 100. Adjust X10 range until Model 3 reads 40K CPM.
7. Set Model 3 range at X100 and set pulser multiplier at 1K. Adjust X100 range until Model 3 reads 400K CPM.

MODEL 3 WITH MODEL 44-3

1. Plateau probe with source.
2. Plateau probe with background count.
3. Pick Operating Point, usually at the flattest part of the plateau.

JUNE 4, 1985

Gamma
Counter

2 1

Fume hood
with
drain outlet

LAB. ONE

Gamma
Counter

2

1

Fume hood
with
drain outlet

LAB. ONE

door to lab. 1

Cooler

Work Island

sink
w/drain

LAB. TWO

door to lab. 1

Cooler

Work Island

sink
w/drain

LAB. TWO

CONTROL NO. 7 9 2 8 1